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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,673	10/12/2001	Sergey Lukyanov	CLON-028	1096

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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 12/27/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,673	LUKYANOV ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 October 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19 is/are pending in the application.
- 4a) Of the above claim(s) 13-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12, 18 and 19 is/are rejected.
- 7) ☒ Claim(s) 1, 7-10, 12, 18-19 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office action is in response to the amendment filed October 05, 2004.

Claims 1-19 are currently pending. **Claims 13-17** have been withdrawn. **Claims 1-12 and 18-19** are under examination. Examiner would like to point out that applicants made a further election of SEQ ID No: 1, as required by the restriction requirement mailed June 15, 2004; furthermore the examiner would like to point out that this was not a species election. Therefore in elected **claims 5-12, and 18-19** only the nucleic acid sequence designated as SEQ ID No: 1 is presently under examination.

Withdrawal of Objections and Rejections

The objection of **claims 10-12 and 18-19** because of an informality is withdrawn.

The rejection of **claims 7 and 9** under 35 U.S.C § 112, first paragraph is withdrawn.

The rejection of **claim 5** under 35 U.S.C § 112, second paragraph is withdrawn.

The rejection of **claims 1-3 and 5-7** under 35 U.S.C § 101 as being drawn to non-statutory subject matter is withdrawn.

The rejection of **claims 1-9** under 35 U.S.C § 102(e) as being anticipated by Tsien et al. is withdrawn.

Maintenance of rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Response to applicant's arguments

In view of rejection of **claim 8** under 35 U.S.C § 112, first paragraph for an asserted lack of enablement, in reference to stringent conditions, the applicants urge that the specification clearly defines the term stringent (Page 8, lines 19-31).

In response to the applicants assertion the examiner would like to state that, the rejection of the claim is under 35 U.S.C §112, first paragraph (lack of enablement) and not 35 U.S.C §112 second paragraph (failing to particularly point out and distinctly claim the subject matter which applicants regards as the invention). It is noted that specification has clearly defined EXAMPLES of stringent conditions; however a person skill in the art would not be able to know which particular stringent conditions are used, unless the specific stringent conditions, which are used in the hybridizing assay, are cited in the claim. The applicants need to amend the claim by inserting the specific

stringent conditions that are to be used for hybridizing isolated nucleic acids to the claimed nucleic acid molecule in order to overcome the rejection.

New rejection(s) and Objections

Claim Objections

Claims 1, 7-10, 12, 18-19 are objected to because of the following informalities:

Claims 1, 7-10, 12, 18-19 are objected to because the species/family name in the claims is not italicized, for example *stichodactylidiaen*.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-2, 7, 9-12 and 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to a nucleic acid molecule that encodes a stichodactylidiaen chromoprotein or fluorescent mutant thereof, however, the claimed nucleic acid is only defined by a function (encoding a protein) not a structure, for

example see **claims 1-2, 7, 9-12 and 18-19**. In addition, the encoded protein is a mutant of stichodactylidiaen chromoprotein or fluorescent protein mutant thereof (see for example **claim 1**) and the claim does not define a reference point for the mutation as the protein is defined solely by its properties. The claims encompass a genus of mutants not adequately described in the instant specification. For example, on page 8 of the instant specification it is stated that nucleic acids encoding mutants of the proteins can be generated by random mutagenesis using well known techniques in the art. The mentioned techniques may produce sequence changes that may be substitutions, insertions, deletions, or a combination thereof. Deletions may further include larger changes such as deletions of a domain or exon, for example stretches of 10, 20, 50, 75, 100, 150 or more amino acid residues presenting a genus of species that have not been adequately described in the present application. A person skill in the art would not be to able to readily predict random mutations and envision the detailed chemical structure of the genus of polypeptide mutants.

The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states, "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed." (See page 1117.) The specification does not it clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116), As discussed above, the skilled artisan cannot envision the detailed chemical structure of the encompassed genus of polypeptides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481 at 1483. In *Fiddes*, claims directed to mammalian FGF' s were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore for all of these reasons the specification lacks adequate written description, and one skill in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 7-12 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-5, 8-10, 12-15, 22-23** of copending Application No. 10/006922. Although the conflicting claims are not identical, they are not patentably distinct from each other because **claims 1-2, 7-12 and 18-19** of the present application are drawn to a nucleic acid molecule that encodes a stichodactylidiaen chromoprotein or fluorescent mutant thereof. Stichodactylidiaen is a family of organisms that is in the class Anthozoa which is in the phylum Cnidaria. **Claims 1-5, 8-10, 12-15 and 22-23** of copending application No. 10/006922 are drawn to a nucleic acid molecule that encodes a Cnidarian chromoprotein or fluorescent mutant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-2, 7-12 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-3, 5-9 and 15-16** of copending Application No. 10/081864. Although the conflicting claims are not identical, they are not patentably distinct from each other because **claims 1-2, 7-12 and 18-19** of the present application are drawn to a nucleic acid molecule that encodes a stichodactylidiaen chromoprotein or fluorescent mutant thereof. Stichodactylidiaen is a family of organisms that is in the class Anthozoa that is in the phylum Cnidaria. **Claims 1-3, 5-9 and 15-16** of copending application No. 10/081864 are drawn to a nucleic acid molecule that encodes a Cnidarian chromoprotein or fluorescent mutant thereof.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1-12 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over **claims 1-16, 21 and 43** of copending Application No. 10155809. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are directed to nucleic acids encoding far-red shifted anthozoan chromoproteins or fluorescent proteins, whereas the scope of the instant claims is to nucleic acids encoding any kindling fluorescent proteins. The instant claims overlap and encompass those sections of the claims of the copending application, which are directed to fluoroproteins.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

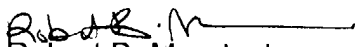
Conclusion

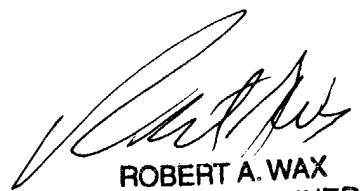
No claims are allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 571-272-0956. The examiner can normally be reached on 9am-5pm, Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Robert B. Mondesi
12-18-06


ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653